

REMARKS

Entry of amended claim 40 is respectfully requested.

In paragraph 3 of the Office Action, the Examiner has acknowledged Applicants' election with traverse of Group I, claims 1-33, 35, 40, 45, 46, 53 and 54 as drawn to the elected compound invention of claim 40 (bottom of specification page 174). In response to the Examiner's request, Applicants cancel non-elected claims 34, 36-39, 41-44 and 47-52. In summary and in furtherance of prosecution, Applicants have canceled claims 1-39 and 41-54.

In paragraph 4 of the Office Action, the Examiner has suggested "if Applicants desire priority under 35 U.S.C. § 119(e), a specific reference to the earlier application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph." Applicants herein submit an amendment claiming priority based on the previously filed provisional application and identified in the filing receipt of the instant application as follows: "This application claims benefit of 60/220,109 filed July 21, 2000." Entry of the amendment claiming priority is respectfully requested.

In paragraph 5 of the Office Action, the Examiner refers to a listing in the application file jacket of an IDS filed on January 3, 2002, Paper No. 4. The Examiner states that Form PTO-1449 was not found in the file and has asked that a copy of the form previously filed be provided along with the references to the extent that such references differ from those filed in Paper No. 5. Enclosed herein is a copy of the Information Disclosure Statement as well as Form PTO-1449 and a copy of the postcard stamped by the Patent Office showing receipt of the papers. Copies of the references cited in said PTO-1449 are also enclosed herein.

Paragraph No. 6 of the Office Action summarizes the status of the claims. The Examiner states, "the claims of Group I, claims 1-33, 35, 40, 45, 46, 53 and 54 are drawn to the elected compound invention, compound #21 of claim 40 (bottom of specification page 174)." As noted above, the Examiner then indicates that the remaining claims are withdrawn from consideration, which withdrawal has been acknowledged by Applicants above. The Examiner then states that the elected claims as drawn to the elected compound #21 of claim 40 are pending and examined on the merits. It is respectfully noted that the Examiner refers to the elected compound invention as compound #21. However, since the compounds appearing in claim 40 have not been numbered, it appears that an error was inadvertently made in counting the compounds identified in claim 40. The compound appearing at the bottom of the specification at page 174 corresponds to the 20th compound appearing in claim 40 rather than the 21st compound thereof. This compound also corresponds to the middle compound appearing on page 19 of the facsimile sent to the Examiner on March 13, 2003, which facsimile included a restatement of the elected claims and a clean copy of those claims. Consequently, in each instance where the Examiner refers to compound #21 in the Office Action, Applicants will understand that reference to refer to the compound appearing at the bottom of the specification at page 174 and otherwise identified as the 20th compound appearing in claim 40.

In paragraph 7 the Examiner states that the claimed invention, as elected in claims 1-33, 35, 40, 45, 46, 53 and 54, is drawn to the elected invention peptide compound #20/54 of claim 40 (bottom of specification page 174), "and enantiomers, stereoisomers, rotamers and tautomers" of elected compound #20 of claim 40. The Examiner states that the specific elected

compound, peptide #20 of claim 40, has been determined to be free of the prior art and is patentable.

However, continuing in paragraph 8, the Examiner rejects the elected claims under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In particular, the Examiner explains that the specification has not defined the structures associated with the broad genus of "enantiomers, stereoisomers, rotamers and tautomers of the elected compound #20 of claim 40." The Examiner concludes that only the structure of elected compound #20 of claim 40 can be determined based on the specification. The Examiner further states, "claim 1 encompasses numerous species that are not further described, namely enantiomers, stereoisomers, rotamers and tautomers of elected compound #20 of claim 40. As fragments will contain different structures from compound #20 of claim 40, there is substantial variability among the species." The Examiner further states "one of skill in the art would not recognize from the disclosure that the Applicant was in possession of the genus of which includes the enantiomers, stereoisomers, rotamers, and tautomers of elected compound #20 of claim 40, and that the specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116)." The Examiner expressly notes (at page 5, lines 2-3) that this rejection is a "written description" rejection rather than an enablement rejection under 35 U.S.C. § 112, first paragraph. This rejection is respectfully traversed.

To begin with, it is respectfully suggested that one of ordinary skill in the art to which the present invention is

directed would be a person having an advanced degree such as a doctorate or a masters degree in the relevant field, e.g., organic chemistry or biochemistry. Consequently, such a person skilled in the art would immediately recognize that compound #20 has asymmetric carbon atoms at positions 4, 7, 10, 13, 16 and 19, the carbon at position 19 being diastereomeric (counting carbon positions beginning at the extreme left of the compound as illustrated). Furthermore, it is noted that compound #20 is shown in stereoisomeric form such that the bond at carbon positions 16 and 17 is illustrated as a dashed wedge, indicating that the groups associated with such bond are behind the plane of the molecule. Therefor, one of skill in the art would understand that the inventors were clearly in possession of an invention which included stereoisomeric forms of the compound as expressly noted in the claims.

Furthermore, the Examiner's attention is invited to the specification at several places as further evidence that the inventors were in possession of the invention as presently expressed in the claims. To begin with, at page 13, beginning at line 5, the inventors state "Unless defined otherwise, all technical and scientific terms used herein have the same meaning as is commonly understood by one of skill in the art to which this invention belongs." Consequently, although the words "enantiomers, stereoisomers, rotamers and tautomers" are not explicitly defined at the place shown in the specification, such terms are well-known to those skilled in the art such that it is unnecessary to provide dictionary or textbook definitions of these terms; recalling that one skilled in the art to which the invention is directed is a person with an advanced degree. Secondly, the Examiner's attention is invited to page 14 at lines 10-12 wherein the inventors recite, "Also included in the invention are tautomers, rotamers, enantiomers and other optical isomers of compounds of Formula I, Formula II and Formula III,

as well as pharmaceutically acceptable salts, solvates and derivatives thereof." Finally, the Examiner's attention is invited to page 30 beginning at line 27, wherein the inventors state,

"As stated earlier, the invention includes tautomers, rotamers, enantiomers and other stereoisomers of the compounds also. Thus, as one skilled in the art appreciates, some of the inventive compounds may exist in suitable isomeric forms. Such variations are contemplated to be within the scope of the invention."

Were these quotations from the specification not a sufficient demonstration that Applicants were in possession of the invention as claimed at the time of filing, the Examiner's attention is also invited to numerous places throughout the specification wherein the inventors have illustrated the compounds of interest in stereoisomeric form. In particular, the Examiner's attention is invited to page 20 wherein compound #45 is drawn in stereoisomeric form, and this compound corresponds to claimed compound #20. In this illustration of the structure, the chiral centers at carbon positions 4, 7, 10, 13 and 16 are explicitly indicated. Additionally, Table 2 illustrates numerous compounds prepared by the inventors and illustrated as stereoisomers.

In conclusion, it is respectfully submitted that the claim drawn to compound #20, including the reference to enantiomers, stereoisomers, rotamers and tautomers, is fully supported by the specification as filed, and withdrawal of the rejection is respectfully requested.

Applicants respectfully suggest that, in addition to compound #20 of claim 40, compounds #18, 19, 45 and 46 are so structurally similar to allowable compound #20 that such

compounds should similarly be allowed in the present application. In particular, compound #19 differs from compound #20 in that the group at carbon position 7 (counting from the extreme left of the compound in compound #20) is substituted at the terminal position with an isopropyl group rather than a hydrogen group as in compound #20. Similarly, compound #18 includes an isopropyl group at the same position as just noted, as well as one at the initial position on the first carbon and, additionally, is an alternate stereoisomer in that the bond at carbons #16 and 17 are shown to project in front of the plane rather than behind. Compound #45 includes a cyclohexane group at carbon #17 instead of an isopropyl group as in compound #20, and compound #46 includes a further substitution at the terminal carbon position at the extreme right end of the molecule. Otherwise, and in each instance, compounds #18, 19, 45 and 46 are substantially similar to the chemical structure of compound #20. Therefor, it is respectfully requested that these additional compounds be included as allowable subject matter in the present application.

In view of the amendment and remarks herein submitted, allowance of amended claim 40 is respectfully requested.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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